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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: CYNSHI=7

In re Application of: ) Conf. No.: Not Yet Known  
Osamu CYNSHI et al. ) ) Art Unit: Not Yet Known  
Appln. No.: 10/573,036 ) ) Examiner: Not Yet Known  
Filing Date: March 22, 2006 ) ) Washington D.C.  
For: PHARMACEUTICAL COMPOSITION ) ) August 3, 2006  
FOR TREATING FATTY LIVER )  
OR HEPATIC DISEASE )

INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner for Patents  
U.S. Patent and Trademark Office  
Customer Service Window  
Randolph Building, Mail Stop Amendment  
401 Dulany Street  
Alexandria, VA 22314

Sir:

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed before the mailing date of a first office action on the merits or before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 CFR §1.114.

2. In accordance with 37 CFR §1.98, this IDS includes a list (e.g., form BN/SB/08A/B) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. Other than U.S. patent(s) and/or published

U.S. application(s), which 37 CFR §1.98(a)(2)(ii) does not require to be filed unless specifically required by the Office, a copy of each document listed is attached.

3. Documents AH, AI, AJ, AK, AL, AM, and AN are not in the English language. In accordance with 37 CFR §1.98(a)(3), Applicant states an English translation of each document AH, AI, AJ, AK, AL, AM, and AN (or of the pertinent portions thereof), or a copy of an English-language abstract (or claim) is enclosed.

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in 37 CFR §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

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Attorneys for Applicant(s)

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Substitute for form 144 TORONTO CANADA TRADEMARKS		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>		Application Number	10/573,036
		Filing Date	March 22, 2006
		First Named Inventor	Osamu CYNSHI
		Group Art Unit	Not Yet Known
		Examiner Name	Not Yet Known
		Attorney Docket Number	CYNSHI-7
Sheet	1	of	2

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Signature		Date Considered	
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

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of

2

## Complete if Known

Application Number	10/573,036
Filing Date	March 22, 2006
First Named Inventor	Osamu CYNSHI
Group Art Unit	Not Yet Known
Examiner Name	Not Yet Known

Attorney Docket Number CYNSHI=7

## NON PATENT LITERATURE DOCUMENTS / OTHER INFORMATION

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AL	M. Uchiyama et al., "Lipid Peroxides and organism", <u>Japan Scientific Societies Press, Tokyo</u> , pages 293-295, 1985.	X
	AM	M. INOUE, "Active oxygen and pathogenesis - To bedside for fear of disease", <u>Japan Scientific Societies Press, Tokyo</u> , pages 379-390, 1992	X
	AN	A. PAR et al., "Oxidative stress and antioxidant defense in alcoholic liver disease and chronic hepatitis", <u>Orvosi Hetilap</u> , Vol. 141(30), pages 1655-1659, 2000.	X
	AO	C. LOGUERCIO et al., "Oxidative Stress In Viral And Alcoholic Hepatitis", <u>Free Radical Biology &amp; Medicine</u> , Vol. 34, No. 1, pages 1-10, 2003.	
	AP	T. ZIMA et al., "Oxidative Stress, Metabolism of Ethanol and Alcohol-Related Diseases", <u>Journal of Biomedical Science</u> , Vol. 8, pages 59-70, 2001.	
	AQ	M. I. PRINCE et al., "Oral antioxidant supplementation for fatigue associated with primary biliary cirrhosis: results of a multicenter, randomized, placebo-controlled, cross-over trial", <u>Aliment Pharmacol. Ther.</u> , No. 17, pages 137-143, 2003.	
	AR	K. HOUGLUM et al., "A Pilot Study Of The Effects Of d-a-Tocopherol on Hepatic Stellate Cell Activation in Chronic Hepatitis C", <u>Gastroenterology</u> , No. 113, pages 1069-1073, 1997.	
	AS	Paul ANGULO, "Nonalcoholic Fatty Liver Disease", <u>New England Journal of Medicine</u> , Vol. 346, No. 16, pages 1221-1231, April 18, 2002.	
	AT	Joel E. LAVINE, "Vitamin E treatment of nonalcoholic steatohepatitis in children: A pilot study", <u>The Journal of Pediatrics</u> , Vol. 136, No. 6, pages 734-738, 2000.	
	AU	T. HASEGAWA et al., "Plasma transforming growth factor-β1 level and efficacy of α-tocopherol in patients with non-alcoholic steatohepatitis: a pilot study", <u>Aliment Pharmacol. Ther.</u> , No. 15, pages 1667-1672, 2001.	
	AV	O. CYNSHI et al., "Antiatherogenic effects of the antioxidant BO-653 in three different animal models", <u>Proc. Natl. Acad. Sci.</u> , Vol. 95, pages 10123-10128, August 1998.	

Examiner Signature	Date Considered
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.